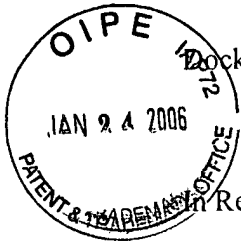


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Docket Number: 071419-0272813

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re the Application of

ARTHUR E UBER III, et al.

Group Art Unit: 3737

Application No.: 09/545,582

Examiner: Ruth Smith

Filed: April 7, 2000

Confirmation No.: Unknown

For: PATIENT INFUSION SYSTEM FOR USE WITH MRI

OVERVIEW OF LITIGATION INVOLVING '602 PATENT AND '648 PATENT

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Overview is being provided to give the Office information regarding litigation involving United States Patent No. Re. 37,602 ("the '602 Patent") and United States Patent No. Re. 36,648 ("the '648 Patent"). The present reissue application is a continuation of the '648 patent, while the '648 patent was reissued as the '602 patent.

I. ITC CASE – '648 PATENT

In 2000, an investigation was commenced at the International Trade Commission ("ITC") regarding infringement of Medrad's '648 patent by Mallinckrodt, Inc., Liebel-Flarsheim Co., and Nemoto Kyorindo Co., Ltd. ("the respondents"). The device accused of infringement was the Optistar MR injector, used for injecting contrast solution into patients during magnetic resonance imaging procedures. Medrad alleged that the Optistar infringed several claims of the '648 patent.

In response, the respondents denied Medrad's allegations and further alleged that the '648 Patent was invalid on several bases and unenforceable due to alleged inequitable conduct. The investigation proceeded through a portion of the discovery phase, but was concluded after the administrative law judge ruled that the '648 patent was invalid because Medrad did not submit Supplemental Reissue Declarations during the prosecution of the patent. *See* Exhibit 1 hereto, Order No. 16, Initial Determination granting motion for summary determination. Medrad submits that the initial determination in the ITC case will not be applicable to the facts of the present application, in that Medrad will submit supplemental reissue declaration in this application, thereby avoiding the error in the '648 patent.

Medrad has disclosed to the Patent Office a number of documents regarding the defenses raised by respondents in prior Information Disclosure Statements in the present application.

II. DISTRICT COURT LITIGATION – '602 PATENT

Following the ITC litigation, Medrad filed a reissue patent application seeking to correct the error made during prosecution of the '648 patent – the same error on which the ITC summary determination of invalidity was based. On March 26, 2002, this reissue application issued as the '602 patent.

Medrad then added the '602 patent to an already-existing case in the United States District Court for the Western District of Pennsylvania entitled "Medrad, Inc. v. Tyco Healthcare Group LP, Mallinckrodt, Inc., Liebel-Flarsheim Co., and Nemoto Kyorindo Co., Ltd." The device accused of infringement of the '602 patent was again the Optistar injector, now sold by Tyco Healthcare (which had acquired Mallinckrodt and Liebel-Flarsheim). The '602 litigation proceeded through the end of fact discovery and expert discovery.

In the '602 litigation, the parties filed numerous documents with the court and served numerous documents on each other as asserted support for their positions and to rebut the allegations presented by the opposing party. A number of categories of those documents are discussed below:

A. Pretrial Statements

In preparation for the trial in the '602 litigation, both parties were required to prepare and file Pretrial Statements, including a summary of the evidence to be introduced at trial on the issues in dispute, including invalidity, inequitable conduct, infringement, and others. Those Pretrial Statements are attached hereto as Exhibits 2 and 3 for reference.

B. Expert Reports

Two sets of expert reports were generated by Medrad and the defendants in the '602 litigation -- the first round in 2003 and the second in 2005. The expert reports that relate to invalidity and inequitable conduct issues will be provided to the Patent Office in the forthcoming IDS.

C. Summary Judgment Motions

Medrad and the defendants also filed a number of summary judgment motions in the '602 litigation, and the summary judgment papers that relate to invalidity and inequitable conduct issues will also be provided in the forthcoming IDS.

D. Section 282 Notice of Prior Art

The defendants also served a Notice Under 35 U.S.C. Section 282, identifying the prior art on which their invalidity allegations were based. The Defendants cited a wide variety of references in this document as asserted support of their allegations. The Section 282 Notice document will also be provided in the forthcoming IDS.

E. District Court Ruling on Summary Judgment

One of the defendants' summary judgment motions was directed to whether the error corrected in the '602 patent was within the types of error correctible by reissue under 35 U.S.C. Section 251. The District Court ruled in favor of defendants on this point and found that the '602 patent was invalid, in that Section 251 did not permit reissue to correct Medrad's failure to submit Supplemental Reissue Declarations. *See* Exhibits 4 and 5, initial and corrected rulings by the District Court. As a result of this ruling, the case is currently on appeal to the Court of Appeals for the Federal Circuit.

Medrad respectfully submits that the summary judgment ruling in the '602 litigation is not applicable to the facts of the present application, which is not directed to correcting the type of error that was addressed in the '602 application. The present application addresses the correction of claiming errors that are plainly within the scope of Section 251.

F. District Court Rulings on Claim Construction

The District Court construed a number of terms in the claims of the '602 patent during a *Markman* proceeding. The court's two rulings on claim construction are attached as Exhibits 6 and 7 hereto.

III. CONCLUSION

Medrad respectfully submits the present Overview for discussion, and will file a more detailed IDS addressing the documents discussed herein.